REMARKS

Claims 62, 64-65, 67-70 are under prosecution in this case. Claims 62, and 64-65, have been amended to better define the subject matter which Applicants regard as the invention. Claims 63 and 66 have been canceled without prejudice. New claim 70 has been added to better claim the subject matter which Applicants regard as the invention. Support is found throughout the Specification, in particular, from page 9, line 7 to page 12, line 20. No new matter has been added with this Amendment.

Claim Rejections under 35 U.S.C. § 112:

Claims 62-69 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Applicants respectfully traverse this rejection.

The Office Action alleges that the recitation of the phrase "composition comprising an antigen of an inactivated or attenuated virus and a hemagglutinin" recited in claim 62 is confusing and unclear. Without acquiescing to this aspect of the rejection and in the interest of advancing the prosecution of this application, claims 62 has been amended to recite an immunogenic composition comprising an inactivated or attenuated virus. Claims 63 and 66 have been canceled without prejudice. Claims 64-65 have been amended to better define the subject matter. New claim 70 has been added to better claim the subject matter which Applicants regard as the invention. With the entry of this Amendment, claims 62, 64-65, and 67-70 are considered to be clear and definite. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claims 62-69 are rejected under 35 U.S.C. § 112, first paragraph, on the ground that the Specification does not provide enablement for using an antigen and a hemogglutinin isolated

from an inactivated or attenuated virus to induce an immune response. Claims 62-69 are further rejected as allegedly containing subject matter not sufficiently described in the Specification. Applicants respectfully traverse these rejections.

With the entry of the present Amendment, amended claim 62 defines a method for inducing a humoral immune response in a CD4+ T cell deficient subject by administering a composition of inactivated or attenuated virus. Accordingly, the issues raised in the Office Action are no longer applicable. Withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claim rejections under 35 U.S.C. § 102:

Claims 62-69 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by either Miotti *et al.*, Dominic *et al.*, Compans *et al.*, Murphy *et al.*, Muster *et al.*, Li *et al.*, Pales *et al.*, or Budowsky *et al.* Applicants respectfully traverse this rejection.

Claim 62 has been amended to recite a method for inducing a humoral immune response in a CD4+ T cell deficient human or animal by administering to said human or animal an immunogenic composition comprising an inactivated or attenuated virus. Applicants submit that none of the cited references teaches the claimed invention.

Miotti *et al.* describes the studies of immunizing HIV infected subjects with influenza subvirion vaccine, hemagglutinin.

Dominic *et al.* describes a method of DNA based immunization in which a DNA vaccine encoding the HA gene was administered to produce HA antigen. The teachings of this reference have little relevance to the invention.

Compans *et al.* teaches a vaccine composition containing virus subunits derived from an intact virus.

Murphy *et al.* describes a method for immunization with an inactivated RSV or purified F glycoprotein in rats.

Muster *et al.* describes an immunization study using a chimeric influenza virus containing a HIV peptide epitope in mice.

Li *et al.* describes the use of chimeric influenza virus expressing an epitope of HIV to induce antibodies in mice.

Pales *et al.* describes several approaches to induce a more effective immune response against an HIV epitope using various recombinant influenza virus vaccines in mice.

Budowsky *et al.* describes effects of inactivation of viral components by beta-propriolactone on inducing an immune response.

In summary, none of the cited references teaches the invention, i.e., a method of inducing an immune response in a subject deficient in CD4+ T cells by using a composition containing an inactivated or attenuated virus. Therefore, the claims as amended are not anticipated by the cited references.

The Office Action alleges that "the limitation of a subject deficient in CD4+ T cells in the preamble language is *just an intended use of same structurally and functionally composition*" (emphasis added) by citing Bristol-Meyers Squibb Company v. Ben Venue Laboratories 58 USPQ2d 1508 (CAFC 2001).

Applicants do not agree. The limitation of a subject deficient in CD4+ T cells recited in the claims is not just an intended use. The invention is practiced in such subjects. This invention was made possible because the inventors discovered for the first time that an immune response can be induced in a CD4+ T cell deficient animal by administering inactivated influenza virus.

The cited case (Bristol-Meyers Squibb Company v. Ben Venue Laboratories) deals with a claim directed to the administration of an anticancer drug in which the preamble is the intended purpose and intended result. The preamble therein is the expression of efficacy and necessary consequence of practicing the method. By contrast, the invention herein represents a case of new use of a process because the method of the invention is practiced in the CD4+ T cell deficient subjects. This use was not known and was not expected to work until the inventors demonstrated it for the first time. The state of the art was such that it was believed that CD4+ T cells are required for inducing a humoral immune response. (*See* Oxenius *et al.* [1998] *Adv. Immunol.* 70:313-367 and Parker D.C. [1993] *Annu. Rev. Immunol.* 11:331-360, both of record herein.) Thus, it was not expected that inactivated influenza virus would be effective in inducing an immune response in the CD4+ T cell deficient animals until the inventors' discovery. The use of the method of the invention in a CD4+ T cell deficient subject is not "only a statement of purpose and the intended result". The invention is a new use of a process and thus patentable, which one skilled in the art would not have made and used until the results of the inventors' studies were disclosed.

In summary, none of the cited references teaches each and every element of the claimed invention and thus the claims as amended are not anticipated by any of the cited references. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

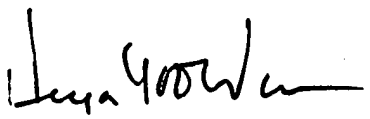
Conclusion:

Based on the foregoing amendments and arguments, it is submitted that this case is in condition for allowance and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the Examiner is invited to call to arrange a mutually convenient time.

It is believed that no fee is due with this submission; however, if this is incorrect, please deduct the appropriate fee for this submission and any extension of time required from Deposit Account No. 07-1969.

Respectfully submitted,



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